EXHIBIT 36

Forced-Air Warming Does Not Worsen Air Quality in Laminar Flow Operating Rooms

Daniel I. Sessler, MD,* Russell N. Olmsted, MPH, CIC, SJMHS,† and Ruediger Kuelpmann, MSc, PhD‡

BACKGROUND: Warm air released by forced-air covers could theoretically disturb laminar airflow in operating rooms. We thus tested the hypothesis that laminar flow performance remains well within rigorous and objective standards during forced-air warming.
METHODS: We evaluated air quality in 2 laminar flow operating rooms using a volunteer "patient" and heated manikin "surgeons." Reduction in tracer background particle counts near the site of a putative surgical incision was evaluated as specified by the rigorous DIN 1946-4:2008-12 standard. Results were confirmed using smoke as a visual tracer.
RESULTS: Background tracer particle concentrations were reduced 4 to 5 log by the laminar flow system, and there were no statistically significant or clinically important differences with a forced-air blower set to off, ambient air, and high temperature. All values remained well within the requirements of the DIN 1946-4:2008-12 standard. Activation of a forced-air warming system did not create an upward draft or interfere with normal and effective function of the laminar flow process.
CONCLUSIONS: Our results, based on quantitative performance testing methods, indicate that forced-air warming does not reduce operating room air quality during laminar flow ventilation. Because there is no decrement in laminar flow performance, forced-air warming remains an appropriate intraoperative warming method when laminar flow is used. (Anesth Analg 2011;113: 1416–21)

Both general and neuraxial anesthesia impair thermoregulation. Consequently, nearly all unwarmed surgical patients become hypothermic.[1,2] Randomized trials have shown that mild hypothermia promotes bleeding and increases transfusion requirement,[3] increases the risk of morbid myocardial events,[4] and prolongs drug metabolism[5–7] and postoperative recovery.[8] Furthermore, independent randomized trials have shown that forced-air warming substantially decreases the risk of surgical site infection.[9,10] Practice guidelines therefore emphasize the importance of maintaining perioperative normothermia.[11,12]

According to the Centers for Disease Control and Prevention, "… for most surgical site infections, the source of pathogens is the endogenous flora of the patient's skin, mucous membranes, or hollow viscera.…"[13] There has nonetheless been some concern that forced-air warming might disperse bacteria within operating rooms. Six studies, however, convincingly demonstrated that properly used forced-air systems do not increase bacterial counts.[14–19]

Whether unidirectional laminar flow systems reduce the risk of surgical site infection remains controversial.[20–22] They are nonetheless sometimes used in the United States for orthopedic procedures, and more frequently in Europe for a variety of operations. A theoretical concern is that warm air released by forced-air covers might disturb laminar airflow in operating rooms.[23] We thus tested the hypothesis that laminar flow performance remains well within rigorous and objective standards during forced-air warming.

METHODS

We evaluated the effect of forced-air warming on laminar flow performance under 3 test conditions: (1) controller off (no air), (2) forced-air controller set to provide ambient (cool) air, and (3) forced-air controller set to high (43°C ± 1.5°C). Under each circumstance, we first qualitatively evaluated the effect of forced-air warming by using a smoke plume to trace airflow patterns over the operating room table. We then quantified tracer particle counts near the site of a putative incision and compared this value with the overall background level of particulates within the room. These tests were conducted with realistic surgical draping and a conscious volunteer on the operating room table. As a reference, we also tested particle counts without a volunteer or draping.

Two different kinds of blankets were tested: Bair Hugger model 522 upper body blanket and model 635 underbody blanket (Arizant Healthcare, Eden Prairie, MN). The blankets were attached to a forced-air warming system unit (Arizant model 750). For each blanket, each of the 3 different test conditions above was studied. Airflow to the 522 blanket from the model 750 blower is approximately 43 cfm (cubic feet per minute); airflow to the 635 blanket is approximately 46 cfm. Tests were conducted within class 1a operating rooms at 2 different hospitals (Amersfoort and

From the *Department of Outcomes Research, Cleveland Clinic, Cleveland, Ohio; †Infection Prevention & Control Services, St. Joseph Mercy Health System, Ann Arbor, Michigan; and ‡Beuth University of Applied Sciences, Berlin, Germany.

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Ruediger Kuelpmann, MSc, PhD, is currently affiliated with the Lucerne University of Applied Sciences and Arts, School of Engineering and Architecture, Lucerne, Switzerland.

Reprints will not be available from the authors.

Address correspondence to Russell N. Olmsted, MPH, CIC, SJMHS, Infection Prevention & Control Services, St. Joseph Mercy Health System, 5301 E. Huron River Dr., Ann Arbor, MI 48106-0995. Address e-mail to olmstedR@trinity-health.org; see also: www.OR.org.

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Figure 1. Illustration of testing procedure setup and key elements of the test conditions. The concentration of particles at the surgical site was assessed at the location of the test point just above the volunteer's abdomen. Heated manikins represent the presence of surgical staff and allow controlled, repeatable testing of the impact of various experimental conditions on laminar flow.

Utrecht, Netherlands). Each operating room was equipped with a laminar flow system designed and installed by Telstar-LUWA (Baarn, Netherlands) and certified by an independent testing agency (Hybeta GmbH, Munster, Germany).

The relevant United States' standard for laminar flow operating rooms is ASHRAE 170, which is incorporated into the 2010 edition of *Guidelines for Design and Construction of Health Care Facilities*.[a] This standard specifies design features of laminar flow operating rooms, including a unidirectional (downward, vertical) supply over the operating room table with returns located at various heights around the operating room. Filtration, temperature, humidity, and at least 20 air exchanges per hour are also specified. Laminar flow operating rooms must be commissioned after being built, a process that focuses on assuring that environmental conditions in the operating room meet the design elements for air exchanges per hour, temperature, humidity, and room pressurization. However, United States' standards for laminar flow operating rooms do not require quantitative testing of particle counts. We therefore used a standard developed in Germany for quantifying adequate function of laminar flow operating room ventilation systems.[24] This standard, DIN 1946-4:2008-12, was chosen because it is objective and more rigorous than United States' standards.

The test method is fully described in Annex C of DIN 1946-4:2008-12, but briefly summarized as follows. Before each test, an aerosol generator and distribution apparatus (Topas GmbH, Dresden, Germany) was installed surrounding the operating room table. The purpose of this system was to generate a controlled flow of aerosol particles composed of diethylhexyl sebacate, a synthetic oil that is safe to breathe in low concentrations. Submicron (0.5–1.0 μm) particles from the aerosol generator were distributed into the operating rooms from 6 specified locations near the operating room table. Particle generation was monitored and carefully controlled to provide a constant particle concentration throughout all studies. The intensity of the reference particle load is held constant and high enough to allow for a 5-log particle reduction between the concentration at a test point and the exhaust airflow of the room. Because diethylhexyl sebacate has a low vapor pressure, the size distribution of the oil particles changes little over time.

Both the reference particle load and particle concentration at the test point were measured by a particle counter (Model 2408; Met One Instruments, Grants Pass, OR). Before any testing with forced-air warming blankets, the effectiveness of the laminar system within each room was verified against the requirements of the DIN 1946-4:2008-12 standard. Both rooms exceeded the minimal requirements for laminar flow operating rooms.

To evaluate the effects of forced air on laminar flow efficacy, a conscious volunteer was positioned supine on an operating room table and draped as though for abdominal surgery. Because 2 different forced-air covers were tested, the surgical draping was appropriately rearranged between each test. The forced-air blower was positioned on the floor at the volunteer's left side, near where the anesthesiologist would normally sit during surgery (Fig. 1).

Two surgical lamps were operated at maximal intensity. Additionally, 6 heated manikins were deployed around the operating room table: 2 on each side and 2 behind the anesthesia screen. Heat sources were integrated into the manikins to achieve a homogeneous surface temperature of 37°C over the entire model body. The total heat output of the manikins was 800 W, which is approximately the amount expected from humans in operating room conditions.

The standard requires an emitted particle source strength (particle flow rate) of $Q_{Ref} = 6.4 \times 10^9$ particles/min. This makes it possible to measure a particle reduction ratio of 5

[a]Facility Guidelines Institute. Guidelines for Design and Construction of Healthcare Facilities. 2010. Available at: http://www.fgiguidelines.org. Accessed May 13, 2011.

log steps between the concentration at a test point within the clean supply air section and the exhaust airflow for rooms that have a ventilation flow of up to 10,000 m^3/h. The resulting background concentration then becomes the (reference) concentration of $C_{Ref} = 35.3 \times 10^6$ particles/m^3 = (1×10^6 particles/ft^3). The setting of the particle generator was adjusted to provide the required particle source strength and was verified before testing began.

The inlet of the particle detector was positioned 10 cm over the volunteer's abdomen to measure the particle concentration (C_X) near a putative abdominal incision. The intake flow rate of the detector was 0.003 m^3/min and the measurement time for each sample was 1 minute.

The standard defines protective effect (PE) as $PE_X = -\log (C_X/C_{Ref})$. PE is therefore the log reduction of particle concentration at the test point (putative surgical site) relative to reference load of particles in the room. A PE = 2.0 corresponds to a 2-log (i.e., 100-fold) reduction in particle C_X; this is the normative threshold for certifying laminar flow operating rooms. A PE = 5.0 (i.e., a 5-log reduction) is the upper limit that can be reliably measured with the instrumentation specified in the DIN 1946-4:2008–12 standard. Five 1-minute samples of particle C_X were taken for each test condition. PE was calculated using the worst of 5 measurements.

Statistical significance of the log reduction in particle C_X was analyzed using analysis of variance 1-factor and 2-factor tests, with replication. The differences in C_X between test conditions and between blankets were tested for statistical significance to 95% confidence level. Data obtained at the 2 different hospitals were pooled because the factors of interest were the cover type and blower setting. Because C_X is the only experimental input to PE_X, the statistical significance of 1 measure applies equally to the other. Results are presented as particle C_X or log reductions in particle C_X and standard deviations; $P < 0.05$ was considered statistically significant.

After particle concentration measurements were finished, a portable vapor generator (OTTEC Technology GmbH, Ronnenberg, Germany) was used to visualize the airflow in and around the laminar flow area. Although qualitative, this technique provided visual insight into differences between test conditions.

An independent testing agency (Hybeta GmbH) conducted all quantitative and qualitative testing. They certified that the methodology complied with the DIN 1946-4:2008–12 standard.

RESULTS

With the Arizant 522 upper body cover, background particle C_X were reduced approximately 5 log by the laminar flow system, and there were no statistically significant or clinically important differences among the 3 blower settings: off, ambient air, and high (Fig. 2). With the Arizant 635 underbody cover, background particle C_X were reduced approximately 4 log by the laminar flow system, and there were no statistically significant or clinically important differences among the 3 blower settings: off, ambient air, and high (Fig. 3).

Neither of the forced-air covers, model 522 and model 635, exhibited any negative impact on the PE of the operating room's ventilation and air conditioning compared with the baseline reference load. Table 1 shows that the PE for each combination of draped operating room, cover, and blower settings reduced background particle counts 3 to 5 log, easily exceeding the 2-log reduction required by DIN 1946-4:2008-12 standards (Table 1).

It is also interesting to note that the PEs for configurations with realistic surgical draping are much better than the nondraped configuration often used for qualifying operating rooms. It seems that the PE of laminar flow may,

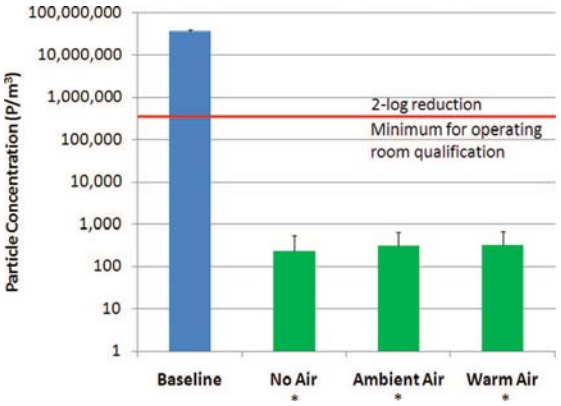

Figure 2. Mean particle concentration at the surgical site (green) versus the background (baseline) particle load (blue) in operating rooms tested with an Arizant 522 upper body forced-air blanket. Three different test conditions are shown: forced-air warming system set to off ("No Air"), ambient ("Ambient Air"), or high ("Warm Air"). Each of the measurements at the surgical site was highly statistically significantly less than the baseline concentration ($P < 0.001$); however, there were no statistically significant differences among the 3 surgical site measurements ($P = 0.39$). Error bars are 95% confidence intervals. The horizontal red line shows the 2-log reduction in background particles that defines adequate laminar flow performance.

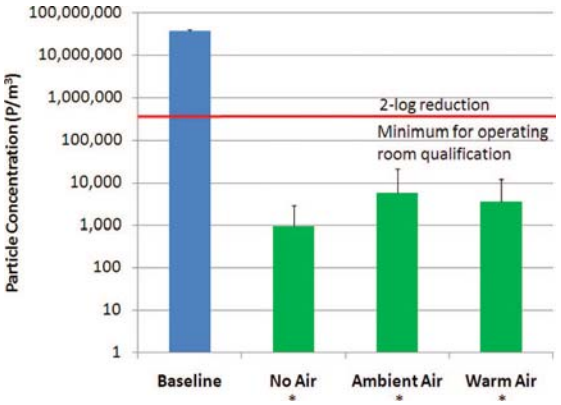

Figure 3. Mean particle concentration at the surgical site (green) versus the background (baseline) particle load (blue) in operating rooms tested with an Arizant 635 underbody forced-air blanket. Three different tests conditions are shown: forced-air warming system set to off ("No Air"), ambient ("Ambient Air"), or high ("Warm Air"). Each of the measurements at the surgical site was highly statistically significantly less than the baseline concentration ($P < 0.001$); however, there were no statistically significant differences among the 3 surgical site measurements ($P = 0.14$). Error bars are 95% confidence intervals. The horizontal red line shows the 2-log reduction in background particles that defines adequate laminar flow performance.

Table 1. Protective Effect Under Various Test Conditions

OR and forced-air cover model number	No surgical draping	Forced-air cover positioned, blower inactive	Forced-air cover positioned, blower set to ambient air	Forced-air cover positioned, blower set to high
OR A/522	2.1 ± 0.1	5.0 ± 0.1	4.8 ± 0.1	4.8 ± 0.1
OR A/635	2.1 ± 0.1	4.0 ± 0.0	3.2 ± 0.0	3.5 ± 0.0
OR B/522	4.6 ± 0.1	4.9 ± 0.1	4.8 ± 0.1	4.8 ± 0.1
OR B/635	4.6 ± 0.1	4.7 ± 0.0	4.7 ± 0.1	4.6 ± 0.1

Results are shown as means ± SDs.

OR = operating room.

Two different ORs were tested, A and B, in different hospitals. Cover 522 is an upper body model; cover 635 is an underbody model. The protective effect is the log reduction in particle counts at the surgical site compared with the background baseline value of the room. (A protective effect of 5.0 corresponds to a 10^5 or 5-log reduction in the number of measured particles.) The protective effect was calculated from the worst of 5 recorded values under each condition.

There were no statistically significant differences among the 3 draped conditions: blower set to off, ambient air, and to high (43.0°C ± 1.5°C) for either cover in either OR.

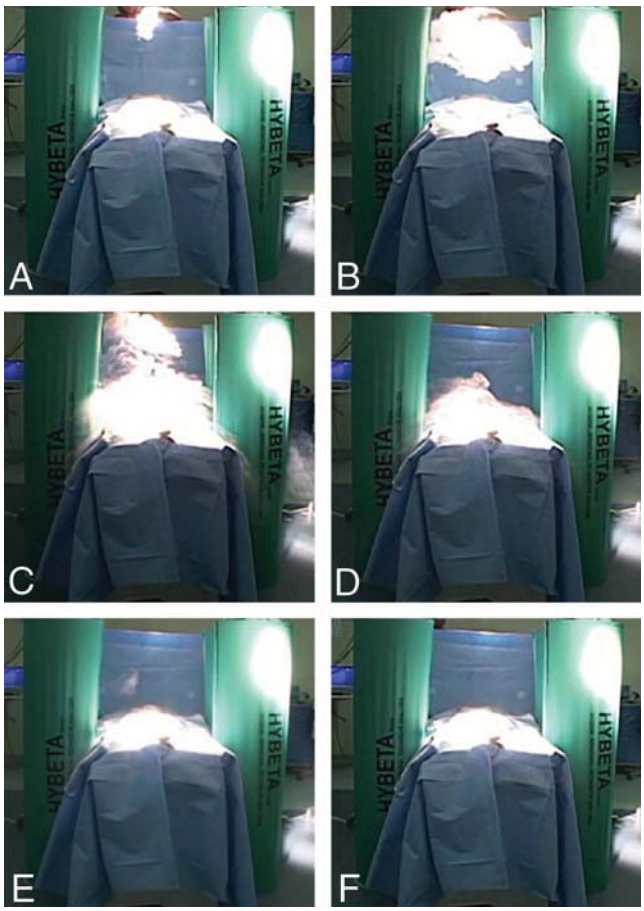

Figure 4. A smoke generator is used to show the airflow patterns above the patient with the forced-air warming system set to "high," which is approximately 43°C. Over the course of 24 seconds, the laminar flow system effectively moved tracer smoke (representing sterile filtered air) downward toward a putative incision. The series of photographs thus shows that the presence of the forced-air warming system did not create an upward draft, or interfere with normal and effective function of the laminar flow process. Contrast was slightly sharpened for clarity, with the same filter applied to each. A, t = 0 seconds; B, t = 3 seconds; C, t = 8 seconds; D, t = 15 seconds; E, t = 18 seconds; and F, t = 24 seconds.

under conditions of actual use, be somewhat better than the operating qualification may indicate.

When smoke was introduced into the airstream from above, with the forced-air blower set to "high," the laminar flow system effectively moved tracer smoke (representing sterile filtered air) downward toward a putative incision over the course of 24 seconds. A series of photographs (Fig. 4) shows that the presence of a forced-air warming system did not create an upward draft or interfere with normal and effective function of the laminar flow process.

DISCUSSION

In response to recent concerns,[23] we asked whether forced-air warming disrupts laminar flow systems and thus potentially augments risk in this narrow circumstance. The answer was clear: both qualitative and quantitative evidence showed that forced-air warming did not compromise air quality in actual clinical laminar flow operating rooms. Furthermore, there was no compromise in operating room air quality with a forced-air cover in place but not activated, forced-air warming activated with ambient room air, or forced-air warming activated with warmed air. Under all conditions, the performance of the tested operating rooms far exceeded the stringent DIN 1946-4:2008-12 standards.

Our results are consistent with computational fluid dynamic models that show that properly designed air-handling systems, combined with natural protective aspects of convective currents up from the patient, are effective in reducing particle concentrations near the surgical site.[25] This analysis was incorporated into the United States' guidelines for design, construction, and operation of operating rooms,[a] and there has been subsequent confirmation of the conclusions of Moretti et al.[16] that forced-air warming does not compromise quality of air or the protection of the operative site.[26]

Given the paucity of evidence that laminar flow is even effective,[20–22] and the strong evidence that forced-air warming reduces infection risk,[9,10] it seems curious that concerns have been raised about the effect of forced-air warming on laminar flow systems. In any case, our results clearly demonstrate that laminar flow systems easily remain within stringent functional specifications during forced-air warming. It is thus reasonable, based on findings from this investigation, to consider forced-air warming to be safe in laminar flow operating rooms.

We tested operating rooms in routine clinical use at 2 separate health care facilities. The exact results will presumably differ somewhat in other operating rooms and facilities. Furthermore, we used static (but heated) manikins to mimic surgical personnel; real people, of course, move more and that movement might, to some extent,

disrupt the laminar flow field. However, our general conclusion, that forced-air warming does not degrade laminar flow performance, is probably broadly applicable.

In summary, forced-air warming is well established as an effective and safe method for maintaining perioperative normothermia. Previous clinical studies show that forced-air warming does not increase dispersion of bacteria in operating rooms.[14–19] We extend these results by showing that activation of forced-air warming does not reduce operating room air quality, even during laminar flow ventilation.

DISCLOSURES

Name: Daniel I. Sessler, MD.
Contribution: This author helped analyze the data and write the manuscript.
Conflicts: The Department of Outcomes Research receives funding from Arizant Healthcare; the department is also funded by various companies that make temperature monitor and management systems. Dr. Sessler has been appointed to a 3M Advisory Board, but has yet to attend a meeting; any fees received will be donated to charity. He has no other personal and financial interest related to this research.
Attestation: Daniel I. Sessler has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.
Name: Russell N. Olmsted, MPH, CIC, SJMHS.
Contribution: This author helped design the study, analyze the data, and write the manuscript.
Conflicts: Russell N. Olmsted consulted for Arizant Healthcare, and has no personal financial interest in this research.
Attestation: Russell N. Olmsted has seen the original study data, reviewed the analysis of the data, approved the final manuscript, and is the author responsible for archiving the study files.
Name: Ruediger Kuelpmann, MSc, PhD.
Contribution: This author helped design the study, conduct the study, analyze the data, and write the manuscript.
Conflicts: Ruediger Kuelpmann received research funding from Arizant Medical, and has no personal financial interest in this research.
Attestation: Ruediger Kuelpmann has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.
This manuscript was handled by: Dwayne R. Westenskow, PhD.

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